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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,745	12/21/2001	Keiichi Kawai	Q67507	2602

7590 03/10/2003

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EXAMINER	
JONES, DAMERON	

ART UNIT	PAPER NUMBER
1616	6

DATE MAILED: 03/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/018,745	KAWAI ET AL.	
	Examin r	Art Unit	
	D. L. Jones	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *14-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESTRICTION INTO GROUPS

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 14-29, drawn to a composition and method thereof wherein the composition comprises a first drug and a second drug wherein the second drug is bucolome.

Group II, claim(s) 14-29, drawn to a composition and method thereof wherein the composition comprises a first drug and a second drug wherein the second drug is cefazolin.

Group III, claim(s) 14-29, drawn to a composition and method thereof wherein the composition comprises a first drug and a second drug wherein the second drug is etoposide.

Group IV, claim(s) 14-29, drawn to a composition and method thereof wherein the composition comprises a first drug and a second drug wherein the second drug is phenylbutazone.

Group V, claim(s) 14-29, drawn to a composition and method thereof wherein the composition comprises a first drug and a second drug wherein the second drug is aspirine.

Group VI, claim(s) 14-29, drawn to a composition and method thereof wherein the composition comprises a first drug and a second drug wherein the second drug is salicylic acid.

Group VII, claim(s) 14-29, drawn to a composition and method thereof wherein the composition comprises a first drug and a second drug wherein the second drug is cefatriaxone.

Group VIII, claim(s) 14-29, drawn to a composition and method thereof wherein the composition comprises a first drug and a second drug wherein the second drug is sulfamethizole.

Group IX, claim(s) 14-29, drawn to a composition and method thereof wherein the composition comprises a first drug and a second drug wherein the second drug is valproic acid.

Group X, claim(s) 14-29, drawn to a composition and method thereof wherein the composition comprises a first drug and a second drug wherein the second drug is nabumetone.

Group XI, claim(s) 14-29, drawn to a composition and method thereof wherein the composition comprises a first drug and a second drug wherein the second drug is 6-methoxy-6-naphthyl acetic acid.

Group XII, claim(s) 14-29, drawn to a composition and method thereof wherein the composition comprises a first drug and a second drug wherein the second drug is ibuprofen.

Group XIII, claim(s) 14-29, drawn to a composition and method thereof wherein the composition comprises a first drug and a second drug wherein the second drug is probenecid.

Group XIV, claim(s) 14-29, drawn to a composition and method thereof wherein the composition comprises a first drug and a second drug wherein the second drug is dansyl-L-asparagine.

Group XV, claim(s) 14-29, drawn to a composition and method thereof wherein the composition comprises a first drug and a second drug wherein the second drug is verapamil.

Group XVI, claim(s) 14-29, drawn to a composition and method thereof wherein the composition comprises a first drug and a second drug wherein the second drug is disopyamide.

Group XVII, claim(s) 14-19 and 21-27, drawn to compositions and methods thereof wherein the compositions comprise a first drug and a second drug wherein the *second drug is not one encompassed in Groups XVI above*.

Note: Claims appearing in more than one Group will be examined to the extent that they read on the elected invention.

2. The inventions listed as Groups I-XVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features because the second drugs are common drugs which do not define a contribution over the prior art. Possible combinations of the first

and second drugs may vary extensively and when the number of combinations are taken as a whole result in vastly different combinations. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, the numerous first and second drug combinations, and the complication in understanding the claimed subject matter imposes a burden on any examination of the claimed subject matter.

3. In accordance with 37 CFR 1.499, Applicant is required in reply to this action, to elect a single invention to which the claims must be restricted. Again, the group of invention is not exhausted as it would be impossible under the time constraints and sheer volume of the subject matter being claimed to generate every possible first and/or second drug combination possible with the instant invention. Therefore, Applicant may choose to elect a single invention by identifying another specific embodiment not listed in the group above and the Examiner will generate a group to that subject matter (for example, if Applicant decides to elect Group XVII wherein the second drug is not one encompassed in Groups I-XVI).

ELECTION OF SPECIES FOR SEARCH PURPOSES

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. Due to the

vast number of possible first and second drug combinations, a precise listing of species (first and second drug combinations) cannot be generated. As a result, the above groups have been generated based on possible second drugs.

5. Applicant is respectfully requested, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Note #1: Applicant is respectfully requested to elect a single species for search purposes. The species should include a nuclide and a first drug.

Note #2: If Applicant elects Group XVII, then Applicant is respectfully requested to identify both the first and second drugs and the nuclide.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

D. L. Jones
Primary Examiner
Art Unit 1616

March 6, 2003